REMARKS

This Response is submitted in reply to the Final Office Action mailed on April 7, 2009. A petition for a two month extension of time is submitted herewith. The Director is authorized to charge $490.00 for the petition for a two month extension of time and any additional fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 0112701-00753 on the account statement.

Claims 1-21 are pending in this application. Claims 9-11 and 15-19 were previously withdrawn. In the Office Action, Claims 1-8, 12-14 and 20-21 are rejected under 35 U.S.C. §102 or, in the alternative 35 U.S.C. §103. For the reasons set forth below, Applicants respectfully submit that the rejections should be reconsidered and withdrawn.

In the Office Action, Claims 1-8, 12-14 and 20-21 are rejected under 35 U.S.C. §102(b) as being unpatentable over or, in the alternative, under 35 U.S.C. §103(a) as obvious over, U.S. Patent No. 6,264,982 to Pruthi et al. (*"Pruthi"*) as evidenced by Polyphenolic constitutents of the flowers of Berberis aristata, Journal of the Indian chemical society, 68 (9): 531-532, 19991 to Sivakumar et al. (*"Sivakumar"*) and Occurrence of carotenoids in fruits of the genus Berberis, Bulletin De L'Academie Polonoise Des Sciences, 13 (5):251-255, 1965 to Bubicz (*"Bubicz"*). Applicants respectfully submit that the cited references fail to disclose or suggest every element of the present claims.

Independent Claim 1 recites, in part, a primary composition comprising at least essential lipophilic and hydrophilic bioactive components of a material selected from the group consisting of whole fruit, vegetable and plant material, excluding insoluble fibers, with improved bioavailability, miscibility and stability in a carrier selected from the group consisting of milk, milk protein-containing carriers and combinations thereof, wherein the essential lipophilic and hydrophilic bioactive components are extracted from the material by milling the material in the milk or milk protein-containing carrier. Similarly, independent Claims 12 and 14 recite, in part, a primary composition comprising at least essential lipophilic and hydrophilic bioactive components of a material selected from the group consisting of whole fruit, vegetable, and plant material, excluding insoluble fibers, and combinations thereof, with improved bioavailability, miscibility and stability in a milk or milk protein-containing carrier, wherein the essential

lipophilic and hydrophilic bioactive components are extracted from the material by milling the material in the milk or milk protein-containing carrier.

Applicants submitted herewith a Declaration under 37 C.F.R. §1.132 ("*Declaration*" attached hereto as Exhibit A) that demonstrates the deficiencies of the prior art with respect to the present claims. As supported by the *Declaration,* and as taught by Applicants' specification, essential bioactive components extracted from fruits or plant materials are well-known and widely used in the food industry. However, conventional techniques for extracting such bioactive components only extract some of the bioactive components from the fruit or plant material. For example, water extraction techniques, in which the bioactive components are extracted from insoluble fibers, preserve the natural image and nutritional functions of the bioactive components but are not very efficient. Solvent extraction techniques, while more efficient than water extraction, still fail to extract a substantial portion of the bioactive components from the fruit or plant material and simultaneously impair the nutritional functions of the bioactive components. See, specification, page 1, line 23-page 2, line 28. Therefore, traditional water and solvent extraction techniques are only able to extract a few compounds of the fruit or plant material, leaving some other bioactive materials in the remaining material. For example, polysaccharides, polyphenols and other non-lipophilic compounds are not extracted together with the lipophilic components such as carotenoids, lipophilic vitamins and other lipids.

As is also supported by the *Declaration*, the essential bioactive components of the present claims are extracted from fruits or plant materials by milling the material in a milk or milk protein-containing carrier. Milling the material contained in the milk or milk protein-containing carrier allows for the formation of much smaller particles of ground plant material, allowing more efficient access by the milk or milk protein-containing carrier to both the water-soluble and oil-soluble bioactives of the plant material. The present compositions, thus, are produced by processes that allow for the extraction of a greater amount of bioactive materials than with traditional water or solvent extraction techniques. The fruit or plant material is mixed in a milk or milk protein-containing medium and separated from insoluble fibers to obtain an aqueous suspension. By using a milk or milk protein-containing carrier to extract the bioactive components from the fruit or plant material, the present claims provide bioactive components with improved miscibility, stability and bioavailability over conventional extraction techniques without the use of organic solvent residues. See, specification, page 3, lines 19-page 4, line 10;

page 7, lines 5-12. Specifically, by using milk or milk proteins, soy-milk or milk-like proteins from plants, the primary composition of the present invention provides a similar profile of the important nutrients like the whole fruit. Furthermore, by also removing the insoluble fibers, the primary composition of the present claims can be efficiently produced. See, specification, page 4, lines 1-3. In contrast, *Pruthi* is deficient with respect to the present claims.

The *Declaration* demonstrates that *Pruthi* fails to disclose or suggest a primary composition comprising at least essential lipophilic and hydrophilic bioactive components of a material selected from the group consisting of whole fruit, vegetable, and plant material, excluding insoluble fibers, and combinations thereof, with improved bioavailability, miscibility and stability as required, in part, by independent Claims 1, 12 and 14. *Pruthi* also fails to disclose or suggest to disclose or suggest a primary composition wherein the essential lipophilic and hydrophilic bioactive components are extracted from the material by milling the material in the milk or milk protein-containing carrier as required, in part, by independent Claims 1, 12 and 14.

As is described in detail in the *Declaration*, Applicants have now performed experimental tests comparing the compositions and methods of making same of the present invention to the compositions and methods of making same of *Pruthi*. Specifically, Applicants have prepared compositions according to the procedure described in column 3, lines 21-29 in *Pruthi* and compositions according to Example 1 of the present specification. The extracts obtained from each composition clearly indicate that the quantity of zeaxanthin dipalmitates (ZP) (a key lipophilic bioactive material from wolfberry) extracted from 20 g of dried wolfberries is significantly higher in the extract obtained from Example 1 of the present specification (34.0 mg) when compared to the extract obtained from the process in *Pruthi* (4.0 mg).

To prepare the composition of *Pruthi*, Applicants used wolfberry powder mixed with milk, boiled the mixture for 2 minutes, cooled the mixture to room temperature, filtered the mixture to remove leaves, dirt, and other particulate and then measured the extraction yield of ZP. As discussed in the *Declaration*, and using spectrophotometer analysis, the resulting extraction yield of ZP was 4.0 mg. The resulting extraction yield was light brown in color.

To prepare the compositions according to the present invention, Applicants followed Example 1 of the specification. In the preparation, for example, Applicants used dried wolfberry and milk to create a mixture. The mixture was wet-milled, decanted and then the extraction yield

of ZP was measured. As discussed in the *Declaration*, and using spectrophotometer analysis, the resulting extraction yield of ZP was 34.0 mg. The resulting extraction yield was orange red in color, indicating a very different amount of carotenoids when compared to the extraction yield of *Pruthi* (light brown).

Therefore, upon experimental testing to compare *Pruthi* against the subject matter of the present claims, it is clear that *Pruthi* is simply an "infusion" process that uses mixing, boiling and filtering. *Pruthi* does not disclose or suggest that the plant cells should be ruptured in order to release the bioactive material and bring milk proteins into contact with insoluble (lipophilic) bioactives. In fact, it is quite evident from the quantity of ZP extracted from the composition of *Pruthi* and the color of the extract, that most of the bioactive material in the intact plant cells cannot be extracted into the aqueous solution. This is in direct contrast to the present claims, which require that the bioactive component be wet-milled in milk, instead of simply mixing with milk, to extract bioactive materials. Accordingly, the process for obtaining the compositions, as well as the resulting compositions, are clearly different than the compositions disclosed in *Pruthi*.

Further, *Pruthi* is entirely directed toward a simple acqueous extraction of components of the Barberry plants. For example, *Pruthi* explicity discloses the following:

> Indian Barberry plant parts are broken into small pieces and then mixed with equal amounts of either water of milk in a first mixing bowl or chamber to produce a first mixture. This first mixture is heated to a boil and is maintained at a boil for 2 to 3 minutes. It is critical that this boiling time is not exceeded, as this will destroy the healing properties of the herbal ingredients. After heating, the first mixture is allowed to cool to room temperature and is then filtered to remove leaves, dirt, and other particulate to yield an extract. All three powders of Karchi, Margosa and Soap Nut powders (as prepared above) are added to the viscous solution of Indian Barberry and thoroughly blended together to achieve a uniform blend for effective healing results and allowed to cool to a solid mass.

See, *Pruthi*, column 3, lines 21-29. Based on this disclosure, it is very clear that the milk of *Pruthi* is used in the same manner as the water during an aqueous extraction. Indeed, the boiling treatment discussed above in *Pruthi* is, as is commonly known in the art, applied for water-extraction. In view of the processing steps cited above, it is also clear that *Pruthi* fails to even

consider using milk proteins to extract lipophilic compounds. In fact, to release lipophilic compounds from the plant cells, a step of "milling" in the presence of milk is needed to achieve good extraction of both water-soluble and oil-soluble bioactives, as is discussed above. At no place in the disclosure does *Pruthi* even mention any milling or grinding process with respect to the Indian Barberry. Accordingly, *Pruthi* cannot disclose that the lipophilic bioactive components have the improved bioavailability, miscibility and stability of the compositions of the present invention that result from milling the fruit or plant material in a milk or milk protein-containing carrier as required, in part, by the present claims.

The Patent Office asserts that *Pruthi* discloses extracting Indian barberry in carrier milk and that, as such, it is deemed that the bioavailability, miscibility and stability are improved. See, Office Action, page 5, lines 6-8. However, as is clearly demonstrated by the attached *Declaration*, the composition of *Pruthi* does not have the the bioavailability, miscibility and stability that is seen with the presently claimed compositions. Applicants submit that comparison of the present invention with the closest prior art *Pruthi* clearly demonstrates very different products and methods of producing same.

Further, nowhere does *Pruthi* disclose that the lipophilic bioactive components have improved bioavailability, miscibility and stability, nor does the Patent Office cite support for such claimed element. In fact, *Pruthi* fails to even use the term "bioactive components" or discuss extraction of both water-soluble and oil-soluble bioactives. In contrast, *Pruthi* is entirely directed toward using water or milk in similar processes to obtain a water-extraction. See, *Pruthi*, column 3, lines 21-29. *Pruthi* fails to disclose any processing steps that involve milling or grinding of the Indian Barberry in milk or milk protein-containing carriers. As such, *Pruthi* fails to disclose or suggest essential lipophilic and hydrophilic bioactive components with improved bioavailability, miscibility and stability in accordance with the present claims. This is in direct contrast to the present invention, which, as discussed above, provides bioactive components with improved bioavailability, miscibility and stability by extracting bioactive components from a fruit or plant material by milling the material in a milk or milk protein-containing carrier instead of an organic solvent.

Applicants note that the claimed element of improved bioavailability, miscibility and stability of the bioactive components was previously added in the amendment dated July 17, 2008 primarily because the Patent Office seemed to suggest in the Office Action dated April 22,

2008, that such a limitation may make the claims allowable over the cited references. Applicants do not believe that such a limitation is necessary because it is inherent in the present claims. By extracting the essential lipophilic and hydrophilic bioactive components from the fruit or plant material by milling the material in a milk or milk protein-containing carrier, the bioavailability, miscibility and stability of the bioactive components is improved over conventional extraction techniques, as is discussed above. As such, because the present claims recite, in part, a primary composition wherein the essential lipophilic and hydrophilic bioactive components are extracted from the material by milling the material in the milk or milk protein-containing carrier, the essential lipophilic and hydrophilic bioactive components necessarily have improved bioavailability, miscibility and stability. For reasons discussed previously, *Pruthi* fails to disclose every element of the present claims.

The Patent Office cites *Sivakumar* solely for the proposition that *Berberis aristata* contains polyphenolic constitutents such as quercetin. The Patent Office cites *Bubicz* solely for the proposition that in the fruits of the 34 species of the genus *Berberis*, the fuits of all the species contain the same carotenoids. As such, neither *Sivakumar* nor *Bubicz* remedy the deficiencies of *Pruthi*.

Accordingly, Applicants respectfully request that the rejection of Claims 1-8, 12-14 and 20-21 under 35 U.S.C. §102(b) as anticipated by or, in the alternative under 35 U.S.C. §103(a) as obvious be reconsidered and withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims that could be clarified in a telephonic interview, the Patent Office is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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EXHIBIT A